

## NEW ZEALAND CONSUMER MEDICINE INFORMATION

### GALANTYL

*Galantamine (as the hydrobromide)*

*Extended release capsules 8 mg, 16 mg, 24 mg*



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### What is in this leaflet

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This leaflet answers some common questions about Galantyl.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Galantyl against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.** You may need to read it again.

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### What GALANTYL is used for

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Galantyl is used to treat mild to moderately severe dementia of the Alzheimer type.

The symptoms of Alzheimer's disease include confusion, memory loss or other changes in behaviour. As the disease progresses, patients find it more and more difficult to carry out their normal daily activities.

The symptoms of Alzheimer's disease are thought to be due to a lack of acetylcholine, a substance which transmits messages between brain cells. Galantyl, which contains the active ingredient galantamine, increases the amount of this substance to help improve or stabilise the symptoms and therefore slow the progress of Alzheimer's disease.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed it for another reason.

Galantyl is not recommended for use in children.

This medicine is available only with a doctor's prescription.

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### Before you take GALANTYL

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**When you must not take it:**

Do not take Galantyl if you have:

- an allergy to any medicine containing galantamine hydrobromide or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin
- severe liver and/or kidney disease

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

***Before you start to take it:***

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have or have had any of the following medical conditions:**

- liver and/or kidney disease
- heart problems
- stomach ulcers
- attacks of sudden abdominal pain
- brain disorders such as seizures or Parkinson's disease
- breathing disorders such as asthma, obstructive pulmonary disease or pneumonia
- recent gut or bladder surgery
- difficulty passing urine

**Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.**

Your doctor can discuss with you the risks and benefits involved.

**Tell your doctor if you are planning to undergo surgery which will require anaesthesia.**

**If you have not told your doctor about any of the above, tell him/her before you start taking Galantyl.**

Your doctor will advise you whether or not to take Galantyl or if you need to adjust the dose or alter your treatment. Since there may be other related conditions that Galantyl is not intended to treat, you should verify with your doctor that you are taking Galantyl for the treatment of mild to moderate Alzheimer's disease.

Initial results from clinical trials in patients with mild cognitive impairment of various causes have

shown a slightly higher mortality rate (higher death rate) in those taking galantamine than those taking placebo (a pill without an active ingredient which is commonly used in clinical trials as a reference for comparison). The reason for this difference is currently not known and may just be due to chance. There is no evidence of increased risk of death in those with mild to moderately severe Alzheimer's disease taking galantamine.

## ***Taking other medicines***

**Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.**

Some medicines and Galantyl may interfere with each other. These include:

- anticholinergic medicines (used to prevent travel sickness, relieve stomach cramps, spasms or diarrhoea)
- cholinergic medicines (e.g. bethanecol and certain medicines used during surgery)
- medicines used to treat Parkinson's disease
- medicines for certain heart problems (such as digoxin, quinidine) or to help lower blood pressure (such as a class of medicine called beta blockers)
- medicines used for breathing problems
- certain medicines used to treat fungal infections (such as ketoconazole) or bacterial infections (such as erythromycin)
- certain medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis
- certain medicines used to treat depression (such as paroxetine, fluoxetine, fluvoxamine)

These medicines may be affected by Galantyl or may affect how well it works. You may need different amounts of your medicines, or you

may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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## **How to take GALANTYL**

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**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions provided with this medicine, ask your doctor or pharmacist for help.**

### ***How much to take***

The dose of Galantyl is gradually increased to the most suitable dose. The necessary dosage steps should be determined by your doctor to suit your needs.

The following scheme is an example of how your doctor may increase the dose:

- Start with 8 mg a day
- After four weeks of treatment, raise the dose to 16 mg a day
- After at least another four weeks of treatment, raise the dose to 24 mg a day

For long-term treatment, up to 24 mg a day is usually suitable but your doctor will determine the dose that is best for you.

If treatment is discontinued for more than several days, tell your doctor. Your doctor will need to re-start your treatment at the lowest dose. This will minimise the chance of experiencing side effects.

### ***How to take it***

Galantyl extended release capsules should be taken once daily in the morning, preferably with food. Be sure to drink plenty of liquids during your treatment to keep yourself hydrated.

**Swallow the capsules whole with a full glass of water.**

### ***How long to take it***

**Continue taking your medicine for as long as your doctor tells you.**

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

### ***If you forget to take it***

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.**

**Do not take a double dose to make up for the dose that you missed.**

**If you have missed more than one dose, or are not sure what to do, ask your doctor or pharmacist.**

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

### ***If you take too much (overdose)***

**Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Galantyl. Do this even if there are no signs of discomfort or poisoning.** You may need urgent medical attention.

Symptoms of an overdose may include muscle weakness or twitch, nausea, vomiting, stomach cramps, excessive production of saliva, tears or sweat, dry mouth, loss of bladder or bowel control, a fast or slow heart beat, chest pain, low blood pressure, dizziness, light-headedness, collapse, seizures, difficulty breathing and hallucinations.

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# While you are taking GALANTYL

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## ***Things you must do***

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Galantyl.**

**Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.**

**If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.** It may affect other medicines used during surgery.

**If you become pregnant while taking this medicine, tell your doctor immediately.**

**If you are about to have any blood tests, tell your doctor that you are taking this medicine.** It may interfere with the results of some tests.

**Keep all of your doctor's appointments so that your progress can be checked.**

## ***Things you must not do***

**Do not take Galantyl to treat any other complaints unless your doctor tells you to.**

**Do not give your medicine to anyone else, even if they have the same condition as you.**

**Do not stop taking your medicine or lower the dosage without checking with your doctor.**

## ***Things to be careful of***

**Be careful driving or operating machinery until you know how Galantyl affects you.**

This medicine may cause dizziness or drowsiness in some people, especially during initial treatment. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

**Be careful when drinking alcohol while you are taking this medicine.**

If you drink alcohol, dizziness or drowsiness may be worse.

**If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.**

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

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## **Side effects**

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Galantyl.**

This medicine helps most people with Alzheimer's disease, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

**Do not be alarmed by the following lists of side effects. You may not experience any of them.**

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor or pharmacist if you notice any of the following and they worry you:**

- nausea, vomiting, diarrhoea, stomach pain or discomfort, indigestion, difficulty swallowing
- low potassium levels in the blood – weakness, muscle cramps, numbness and tingling that begins in the lower extremities
- muscle spasms
- leg cramps, tingling in the hands or feet
- ringing in the ears
- dehydration (sometimes severe) - thirst, lack of fluids
- hallucinations (seeing, feeling or hearing things that are not there)
- mood changes such as agitation or aggressive feelings

- feeling depressed or having thoughts of harming yourself
- low blood pressure – dizziness, light-headedness
- slow, fast or irregular heart beat
- increased sweating
- fever
- skin rashes
- trembling or shakiness
- loss of appetite, weight loss
- drowsiness, tiredness, weakness, feeling unwell, confusion, trouble sleeping, headache
- blurred vision
- falling (sometimes resulting in injury)
- runny or blocked nose
- urinary tract infection
- high blood pressure
- elevated liver enzymes
- yellowing of the skin and eyes
- light coloured bowel motions
- dark coloured urine

Some of these side effects occur mainly during the early stages of treatment, or when the dose of Galantyl is increased. They usually disappear gradually over time. For example, nausea and vomiting tend to pass after a few days.

Some of these effects may be due to Alzheimer's disease but always inform your doctor about any unwanted effect that has occurred while taking Galantyl.

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- signs of allergy such as rash or hives on the skin; swelling of the face, lips, tongue or other parts of the body; wheezing or difficulty breathing
- vomiting blood or material that looks like coffee grounds
- bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea
- fainting, especially if you have a slow or irregular heart beat
- fits (seizures)

- pain or tightness in the chest
- symptoms of stroke which can include collapsing, numbness or weakness of arms or legs, headache, dizziness and confusion, visual disturbance, difficulty swallowing, slurred speech and loss of speech

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Other side effects not listed above may also occur in some people.

## After using GALANTYL

### Storage

**Keep your capsules in the pack until it is time to take them.**

If you take the capsules out of the pack they may not keep well.

**Keep your capsules in a cool dry place where the temperature stays below 25°C.**

Do not store Galantyl or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

**Keep it where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

## Product description

### What it looks like

Galantyl extended release capsules are available in three different strengths:

**Galantyl 8 mg extended release capsules** are hard gelatin capsules with a white body and pink cap printed in black ink "MYLAN" over "GT 8" on both the body and the cap.

**Galantyl 16 mg extended release capsules** are hard gelatin capsules with a white body and pale pink cap printed in black ink "MYLAN" over "GT 16" on both the body and the cap.

**Galantyl 24 mg extended release capsules** are hard gelatin capsules with a white body and pink cap printed in black ink "MYLAN" over "GT 24" on both the body and the cap.

Each blister pack contains 28 extended release capsules.

### Ingredients

Galantyl extended release capsules contain 8 mg, 16 mg or 24 mg of galantamine as the active ingredient.

All capsules also contain:

- hydrogenated vegetable oil
- magnesium stearate
- polyvinyl acetate
- sodium lauryl sulphate
- povidone
- colloidal silicon dioxide
- black printing ink
- gelatin
- titanium dioxide
- Allura red AC

The capsules do not contain lactose or gluten.

## If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

### Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,  
PO Box 11183,  
Ellerslie,  
Auckland.

Telephone: (09) 579 2792

### Date of Information

25 June 2010  
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